

REMARKS

In response to the above-identified Office Action, Applicant amends the application and seeks reconsideration thereof. In this response, Applicant amends Claims 10 and 14. Accordingly, Claims 10-17 are pending.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attachment is captioned, "Version With Markings To Show Changes Made."

In the Office Action mailed May 3, 2002, the Patent Office rejected Claims 10-17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Particularly, the Patent Office rejected Claims 10-17 with respect to "predetermined physiological levels." Also, the Patent Office rejected claims 10-17 under 35 U.S.C. § 112, second paragraph with respect to the "kit".

With respect to "predetermined physiological levels," the Patent Office certainly can appreciate that physiological levels of virtually any component within a mammalian body have been or can be obtained or ascertained by those of skill in the art. Applicant has set forth his understanding of physiological levels for certain hormones in a normal human body for someone in the second or third decade of life. Applicant believes it would be perfectly adequate and satisfy the requirements of 35 U.S.C. §112, first paragraph, to specify only that target physiological levels should be those of a healthy individual between or within the second or third decade of life. Certainly, the Patent Office does not believe that a person of skill in the art (e.g., a physician) could not ascertain what suitable target levels were taught by such a statement. Applicant did more than this, however. Applicant supplied target objective values according to his understanding of physiological levels for that period of life. With regard to indefiniteness (35 U.S.C. §112, second paragraph), Applicant believes no more than "physiological levels" is required to make the claim definite. Applicant pointed out his understanding of physiological levels in the Application (see Table I), but also noted (in a response filed December 6, 2001) that there may be some debate regarding the

precise values in the medical community, but, in the event of such debate, one of skill in the art can use his/her judgment to determine the precision he/she chooses without deviating from the spirit and scope of the claims.

In response to the rejection with respect to the "kit", Claims 10 and 14, for example, set forth the basic elements of the kit as an amount of HGH and an amount of at least one supplemental hormone. Nothing more is required in the kit to classify it as a kit. Representatively, such a kit (including HGH and at least one supplemental hormone) can be packaged and sold together as a single package unit for administration by, for example, a parent or a caregiver to a patient. The amendments presented herein specify that the HGH and at least one supplemental hormones are in effective amounts and administerable form for establishing a regimen for the replenishment of the hormones within a body to physiological levels.

Applicant respectfully submits that the rejections under 35 U.S.C. § 112, second paragraph have been addressed, and Applicant respectfully requests that the Patent Office withdraw the rejections of Claims 10-17 under 35 U.S.C. § 112, second paragraph.

In the Office Action dated May 3, 2002, the Patent Office rejected Claims 10-17 under 35 U.S.C. § 103(a) as obvious over Danielov et al. ("Danielov") (U.S. Patent No. 5,885,974). To the extent that the rejection applies to the amended claims, Applicant respectfully traverses the rejection.

Applicant respectfully submits that Danielov does not teach the required elements or the required amounts of independent Claims 10 and 14. Specifically, Danielov does not teach or provide any motivation for a kit containing effective and administerable amounts of HGH and at least one supplemental hormone to establish a regimen for replenishment of the hormones within a body to physiological levels.

Claims 11-13 are dependent on independent Claim 10, and Claims 15-17 are dependent on independent Claim 14. The dependent claims contain all the limitations of their respective independent claims. Thus, Applicant respectfully submits that Claims 11-13 and 15-17 are not obvious over Danielov, since Danielov does not teach or suggest the desirability of the required claim limitations of independent Claims 10 and

14. Accordingly, Applicant respectfully requests that the Patent Office withdraw the rejections of Claims 10-17 under 35 U.S.C. § 103(a) as being obvious over Danielov.

In the Office Action dated May 3, 2002, the Patent Office rejected Claims 10-17 under the judicially created Doctrine of Obviousness – Double-Patenting as being unpatentable over Claims 26-34 of U.S. Patent No. 5,855,920. To the extent that the rejection applies to the amended claims, Applicant respectfully traverses the rejections. A Terminal Disclaimer to disclaim the terminal portion of the term of any patent that issued from this Application that extends beyond the term of U.S. Patent No. 5,855,920 will be considered once claims are otherwise in a condition for allowance.

#### CONCLUSION

In view of the foregoing, it is believed that all claims now pending (1) are in proper form, (2) are neither obvious nor anticipated by the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Patent Office believes that a telephone conference would be useful in moving the Application forward to allowance, the Patent Office is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to deposit account 02-2666 or any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

Dated: 7/8/02

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on July 8, 2002.

Nedy Calderon  
Nedy Calderon

7/8/02  
Date

ATTACHMENT: VERSION WITH MARKINGS TO SHOW CHANGES MADE

VERSION WITH MARKINGS TO SHOW CHANGES MADEIN THE CLAIMS

The claims are amended as follows:

10. (Amended) A kit for treating symptoms associated with multiple sclerosis comprising:

human growth hormone; and

at least one of the supplemental hormones selected from the group consisting of sex hormone, melatonin, hormone, adrenal hormone, thyroid hormone, and thymus hormone,

wherein the human growth hormone and the at least one of the supplemental hormones is present in an effective amount and in an administerable form for establishing a regimen for replenishment of the human growth hormone and the at least one supplemental hormone within a body to physiological levels.

14. (Twice Amended) A kit for treating symptoms associated with multiple sclerosis comprising:

human growth hormone; and

at least one supplemental hormone selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone,

wherein the human growth hormone and the at least one of the supplemental hormones is present in an effective amount and in an administerable form for establishing a regimen for replenishment of the human growth hormone and the at least one supplemental hormone within a body to physiological levels associated with the second or third decades of an average human subject.